



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Mar Tomo et al.

Serial No.: 08/726,211

Filed: October 4, 1996

For: INHIBITION OF BCL-2 PROTEIN
EXPRESSION BY LIPOSOMAL
ANTISENSE
OLIGODEOXYNUCLEOTIDES

Group Art Unit: 1636

Examiner: Daniel M. Sullivan

Atty. Dkt. No.: UTXC:504

08/17/2004 LWONDIM1 00000018 08726211

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CERTIFICATE OF MAILING
37 C.F.R 1.8

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August 11, 2004

Date

David L. Parker

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be
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construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/UTXC:504.

Applicants respectfully request that the listed documents be made of record in the present case.


Respectfully submitted,

David L. Parker
Reg. No. 32,165
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: August 11, 2004



Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

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Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A72	5,641,662	6/24/97	Debs and Zhu	435	172.1	3/10/93
	A73	5,837,838	11/17/98	Reed and Xu	536	23.1	3/14/97
	A74	5,981,501	11/09/99	Wheeler <i>et al.</i>	514	44	6/07/95
	A75	5,989,912	11/23/99	Arrow <i>et al.</i>	435	375	12/15/98
	A76	6,030,954	2/29/00	Wu and Wu	514	44	6/02/95
	A77	6,042,846	3/28/00	Lopez-Berestein and Tari	424	450	7/09/98

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B21	WO 97/07784 /	3/06/97	PCT			English
	B22	WO 98/14172 /	4/09/98	PCT			English
	B23	WO 98/56905 /	12/17/98	PCT			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C141	Agrawal, "Antisense oligonucleotides: towards clinical trials," <i>TIB Tech</i> , 14(10):376-387, 1996.
	C142	Agrawal et al., "Antisense therapeutics: is it as simple as complementary base recognition," <i>Molecular Medicine Today</i> , 6:72-81, 2000.
	C143	Aisenberg, "Coherent view of non-Hodgkin's lymphoma," <i>J. Clin. Oncol.</i> , 13(10):2656-2675, 1995.
	C144	Baichwal and Sugden, "Vectors for gene transfer derived from animal DNA viruses: Transient and stable expression of transferred genes," In: Kucherlapati R, (ed.) <i>Gene transfer</i> . New York: Plenum Press, pp. 117-148, 1986.

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	C145	Bangham <i>et al.</i> , "Diffusion of univalent ions across the lamellae of swollen phospholipids," <i>J. Mol. Biol.</i> , 13:238-252, 1965.
	C146	Benvenisty and Reshif, "Direction introduction of genes into rats and expression of the genes," <i>Proc. Nat'l Acad. Sci. USA</i> , 83:9551-9555, 1986.
	C147	Chang <i>et al.</i> , "Foreign gene delivery and expression in hepatocytes using a hepatitis B virus vector," ABSTRACT, <i>Hepatology</i> , 14(4):124A, 1991.
	C148	Chen and Okayama, "High-efficiency transfection of mammalian cells by plasmid DNA," <i>Mol. Cell Biol.</i> , 7(8):2745-2752, 1987.
	C149	Chirila <i>et al.</i> , "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides," <i>Biomaterials</i> , 23:321-342, 2002.
	C150	Coffin, "Retroviridae: the viruses and their replication," In: <i>Virology</i> , Fields <i>et al.</i> (eds.), New York: Raven Press, pp. 1767-1847, 1996.
	C151	Cotter <i>et al.</i> , "Human Bcl-2 antisense therapy for lymphomas," <i>Biochimica et Biophysica Acta</i> , 1489:97-106, 1999.
	C152	Coupar <i>et al.</i> , "A general method for the construction of recombinant vaccinia virus expressing multiple foreign genes," <i>Gene</i> , 68:1-10, 1988.
	C153 ✓	Crooke, "Antisense research and application," Springer, NY, 1-50, 1998.
	C154	Crystal, <i>Science</i> , 270:404-410, 1995.
	C155	Deamer and Uster, "Liposome Preparation: Methods and Mechanisms," <i>LIPOSOMES</i> , M. Ostro ed. (1983).
	C156	Dubensky <i>et al.</i> , "Direct transfection of viral and plasmid DNA into the liver or spleen of mice," <i>Proc. Nat'l Acad. Sci. USA</i> , 81:7529-7533, 1984.
	C157	Fecheimer <i>et al.</i> , "Transfection of mammalian cells with plasmid DNA by scrape loading and sonication loading," <i>Proc. Nat'l Acad. Sci. USA</i> , 84(23):8463-8467, 1987.
	C158	Fraley <i>et al.</i> , "Entrapment of a bacterial plasmid in phospholipid vesicles: potential for gene transfer," <i>Proc. Nat'l Acad. Sci. USA</i> , 76(7):3348-3352, 1979.
	C159	Friedman <i>et al.</i> , "CCAAT/enhancer-binding protein activates the promoter of the serum albumin gene in cultured hepatoma cells," <i>Genes & Devel.</i> 3:1314-1322, 1989.

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	C161	Gleave <i>et al.</i> , "Targeting bcl-2 gene to delay androgen-independent progression and enhance chemosensitivity in prostate cancer using antisense bcl-2 oligodeoxynucleotides," <i>Urology</i> , 54(Suppl 6A):36-46, 1999.
	C162	Gopal, "Gene transfer method for transient gene expression, stable transformation, and cotransformation of suspension cell cultures," <i>Mol. Cell Biol.</i> , 5:1188-1190, 1985.
	C163	Graham and van der Eb, "A new technique for the assay of infectivity of human adenovirus 5 DNA", <i>Virology</i> , 52:456-467, 1973.
	C164	Graham <i>et al.</i> , "Characteristics of a human cell line transformed by DNA from human adenovirus type 5," <i>J. Gen. Virol.</i> , 36:59-72, 1977.
	C165	Harland and Weintraub, "Translation of mammalian mRNA injected into <i>Xenopus oocytes</i> is specifically inhibited by antisense RNA," <i>J. Cell Biol.</i> , 101:1094-1099, 1985.
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	C167	Horwich <i>et al.</i> , "Synthesis of hepadnavirus particles that contain replication-defective duck hepatitis B virus genomes in cultured HuH7 cells," <i>J. Virol.</i> 64(2):642-650, 1990.
	C168	Jansen <i>et al.</i> , "bcl-2 antisense therapy chemosensitizes human melanoma in SCID mice," <i>Nature Medicine</i> , 4(2):232-234, 1998.
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	C170	Johnson <i>et al.</i> , "Patterns of survival in patients with recurrent follicular lymphoma: a 20-year study from a single center," <i>J. Clin. Oncol.</i> , 13(1):140-147, 1995.
	C171	Klein <i>et al.</i> , "High-velocity microprojectiles for delivering nucleic acids into living cells," <i>Nature</i> , 327:70-73, 1987.

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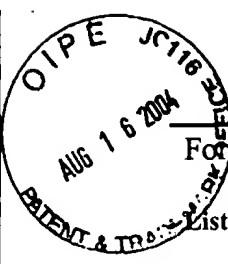
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	C172	Konopleva <i>et al.</i> , "Inhibition of Bcl-2 with liposomal P-ethoxy antisense oligonucleotides induces apoptosis in the presence of high level of Bcl-XL and is critically depending on baseline Bcl-2 levels in AML," <i>J. Amer. Soc. Hematology</i> , 92(10)Suppl. 1, Part 1 of 2, Abstract No. 2100, 1998.
	C173	Mann <i>et al.</i> , "Construction of a retrovirus packaging mutant and its uses to produce helper-free defective retrovirus," <i>Cell</i> , 33:153-159, 1983.
	C174	McDonnell and Korsmeyer, "Progression from lymphoid hyperplasia to high-grade malignant lymphoma in mice transgenic for the t(14;18)," <i>Nature</i> , 349:254-256, 1991.
	C175	Milner <i>et al.</i> , "Selecting effective antisense reagents on combinatorial oligonucleotide arrays," <i>Nature</i> , 15:537-541, 1997.
	C176	Miyake <i>et al.</i> , "Antisense Bcl-2 oligodeoxynucleotides inhibit progression to androgen-independence after castration in the Shionogi tumor model," <i>Cancer Res.</i> , 59:4030-4034, 1999.
	C177	Neilan <i>et al.</i> , "An African Swine fever virus with similarity to the protooncogene <i>bcl-2</i> and the Epstein-Barr virus gene <i>BHRF1</i> ," <i>J. Virol.</i> , 67(7):4391-4394, 1993.
	C178	Nicolas and Rubenstein, "Retroviral vectors," In: <i>Vectors: A survey of molecular cloning vectors and their uses</i> , Rodriguez and Denhardt, (eds.), Stoneham: Butterworth, pp. 494-513, 1988.
	C179	Paskind <i>et al.</i> , "Dependence of moloney murine leukemia virus production on cell growth," <i>Virology</i> , 67:242-248, 1975.
	C180	Palu <i>et al.</i> , "In pursuit of new developments for gene therapy of human diseases," <i>Biotech.</i> , 68:1-13, 1999.
	C181	Pearson <i>et al.</i> , "Identification of an Epstein-Barr virus early gene encoding a second component of the restricted early antigen complex," <i>Virology</i> , 160:151-161, 1987.
	C182	Pihl-Carey, "Disease drug fails in phase III," <i>BioWorld Today</i> , 10:1-2, 1999.
	C183	Potter <i>et al.</i> , "Enhancer-dependent expression of human κ immunoglobulin genes introduced into mouse pre-B lymphocytes by electroporation," <i>Proc. Nat'l Acad. Sci. USA</i> , 81:7161-7165, 1984.
	C184	Ridgeway, "Mammalian expression vectors," In: Rodriguez RL, Denhardt DT, (ed.) <i>Vectors: A survey of molecular cloning vectors and their uses</i> . Stoneham: Butterworth, pp. 467-492, 1988.
	C185	Rippe <i>et al.</i> , "DNA-mediated gene transfer into adult rat hepatocytes in primary culture," <i>Mol. Cell Biol.</i> , 10(2):689-695, 1990.

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	C186	Stratford-Perricaudet and Perricaudet, "Gene transfer into animals: the promise of adenovirus," pp. 51-61, In: <i>Human Gene Transfer</i> , Eds, O. Cohen-Haguenauer and M. Boiron Editions John Libbey Exerptext, France, 1991.
	C187	Szoka and Papahadjopoulos, "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Nat'l Acad. Sci. U.S.A.</i> 75(9):4194-4198, 1978.
	C188	Temin, "Retrovirus vectors for gene transfer: Efficient integration into and expression of exogenous DNA in vertebrate cell genome," In: <i>Gene Transfer</i> , Kucherlapati (ed.), New York: Plenum Press, pp. 149-188, 1986.
	C189	Tur-Kaspa <i>et al.</i> , "Use of electroporation to introduce biologically active foreign genes into primary rat hepatocytes," <i>Mol. Cell Biol.</i> , 6(2):716-718, 1986.
	C190	Verma <i>et al.</i> , <i>Nature</i> , 389:238-243, 1997.
	C191	Wagner <i>et al.</i> , "Antisense gene inhibition by pligonucleotides containing C5 propyne pyrimidines," <i>Science</i> , 260:1510-1513, 1993.
	C192	Wu and Wu, "Evidence for targeted gene delivery to Hep G2 hepatoma cells in vitro," <i>Biochemistry</i> , 27:887-892, 1988.
	C193	Wu and Wu, "Receptor-mediated <i>in vitro</i> gene transformations by a soluble DNA carrier system," <i>J. Biol. Chem.</i> , 262(10):4429-4432, 1987.
	C194	Yang <i>et al.</i> , " <i>In vivo</i> and <i>in vitro</i> gene transfer to mammalian somatic cells by particle bombardment," <i>Proc. Nat'l Acad. Sci. USA</i> , 87:9568-9572, 1990.
	C195	Zelenin <i>et al.</i> , "High-velocity mechanical DNA transfer of the chloramphenicolacetyl transferase gene into rodent liver, kidney and mammary gland cells in organ explants and <i>in vivo</i> ," <i>FEBS Lett.</i> , 280(1):94-96, 1991.
	C196	Ziegler <i>et al.</i> , "Induction of apoptosis in small-cell lung cancer cells by an antisense oligodeoxynucleotide targeting the Bcl-2 coding sequence," <i>J. Nat'l Cancer Institute</i> , 89(14):1027-1036, 1997.

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